

## REMARKS

The Official Action of June 7, 2006 noted an irregularity in the oath/declaration as a result of Applicant's deletion of the claim to the earlier effective filing date of several prior applications under 35 U.S.C. 120 and objected to claims 2 and 23 for certain informalities as noted on the third page of the Action. Claims 20-22 were rejected as being indefinite for failing to particularly point out and claim Applicant's invention under 35 U.S.C. 112, second paragraph. Claims 2, 19, and 24-27 were rejected under 35 U.S.C. 102 as being anticipated by the Perren, *et al.* patent ("Perren"). Claim 2 was rejected under 35 U.S.C. 102 as being anticipated by the Ralph, *et al.* '291 patent ("Ralph '291"). Claims 19-21, 24, and 26 were rejected under 35 U.S.C. 103 as being obvious over the combination of the Ralph '731 or '291 patents in view of Muhanna, and claims 22-23 were rejected under that same section of the Statute as being obvious over the combination of the two Ralph patents and Muhanna in view of the Haldemann patent. All of these objections/rejections are traversed, and in accordance with the requirements of 37 C.F.R. 1.111(b), the basis for traversing these rejections is set out below.

Responsive to the objection to the oath/declaration, attached to this Response is an unexecuted Declaration that omits all reference to Applicant's prior applications. The Declaration is unexecuted because the below-signed Attorney for Applicant was running late and, in his haste, inadvertently neglected to pull it off the printer and tuck it into his file before running out his office door for a meeting with Dr. Pisharodi at the airport here in Houston last Thursday that was convened for the purpose of working on this Response and executing the Declaration. The Declaration is being transmitted to Dr. Pisharodi for execution along with a copy of this Response, and it is respectfully requested that this requirement for a fresh declaration be held in abeyance for such time as is required (expected to be within the next 2-3 weeks) for the Declaration to be executed, returned to Applicant's Attorney, and transmitted to the Office for filing in the captioned application.

Claim 2 has been amended to remedy the informality resulting from the recitation of biasing the implant away from the implant. In making that amendment, and as set out below, Applicant has clarified how the claim was intended to define over the art when it was presented. Claim 23 has also been amended to remedy the informality in the recitation of "the opening." Reconsideration and withdrawal of the objections to claims 2 and 23 is respectfully requested in light of these amendments.

Responsive to the §112 rejection of claims 20-22, claim 20 has been amended to make it clear that if any space remains open after the implant has been inserted into the intervertebral disk space, the space is filled with hydrogel. Similarly, the phrase "the portion of the intervertebral disk

that has been removed” in claim 20 as originally presented has been deleted from the claim and replaced with the reference to “two vertebrae” as suggested in the Action. Reconsideration and withdrawal of the rejection of claims 20-22 is respectfully requested in light of these amendments to claim 20.

Turning now to the prior art rejections, for the following reason, Applicant appreciates the point made in the objection to claim 2 as to the unclear nature of the recitation in claim 2 of the biasing of the implant away from the implant. By remedying that imprecise language, Applicant has been able to make clear what was thought to be a part of the claim as presented but which, with the instruction provided by this objection (and with the benefit of 20-20 hindsight) was not clear. Specifically, by amending claim 2 to recite that the implant comprises a portion, or insert, that is biased away from the remainder of the implant as set out above, Applicant has made it clear how claim 2 defined over the Perren and Ralph ‘291 patents on which the §102 rejection was based. Because neither Perren nor Ralph ‘291 discloses an implant having an insert that is biased away from the remainder of the implant, it was realized that the recitation in the last paragraph of claim 2 as presented (restraining the implant against rotation along its longitudinal axis) was not needed to define over the art, and so Applicant has amended claim 2 to broaden that claim by deleting the last paragraph of the claim. It is requested that the §102 rejection of claim 2 be reconsidered in light of the amendment made to clarify the claim that was made, as set out above, in response to the objection to claim 2.

Referring to claim 19, also rejected under §102 over Perren, Perren does not disclose the removal of a portion of the intervertebral disk as recited in the first paragraph of the claim. To the contrary, at col. 3, lines 60-63, Perren states that the device disclosed in that patent is introduced into the space between two adjacent vertebrae “after removal of the disk from therebetween.” The difference is more than might be apparent from this quotation in that one removes the intervertebral disk when it is intended to replace the disk, and as set out in the background section of Perren (col. 1, lines 8-11, the device described in that patent is used to replace the disk. Applicant’s invention, however, is inserted into the disk space after removal of only a portion of the disk, it being an object of Applicant’s invention to provide (quoting from page 4, lines 8 *et seq.* of the specification of the captioned application)

“a device that maintains the function of the intervertebral disk when implanted between adjacent vertebrae and that is capable of being implanted in a surgical procedure that is minimally invasive and that does not require removal of the entire intervertebral disk.”

Note also that, as a result of the objection to the informality in claim 2 noted in the Action, Applicant reviewed claim 19 and made an amendment of claim 19 to clarify claim 19 and the

manner in which that claim already defined over Perren. Reconsideration and withdrawal of the §102 rejection of claim 19 over Perren is respectfully requested in light of this difference between Applicant's invention as claimed and the disclosure of Perren.

Because they are dependent upon a main claim that is not anticipated by either of the Perren or Ralph '291 patents, claims 24-27 are also allowable. In addition, each of claims 24-27 recites subject matter that is not disclosed in Perren or Ralph '291. For instance, because neither cited patent discloses an insert that is mounted to and biased away from the implant, neither can disclose a spring for biasing that insert away from the implant as recited in claim 24 or restraining the insert until after the implant is inserted into the disk space as recited in claim 25. Similarly, neither cited patent discloses an insert that is comprised of a springy, compressible material as recited in claim 26. Reconsideration and withdrawal of the §102 rejection of those claims is respectfully requested in light of these differences between the claims and the cited Perren and Ralph '291 patents.

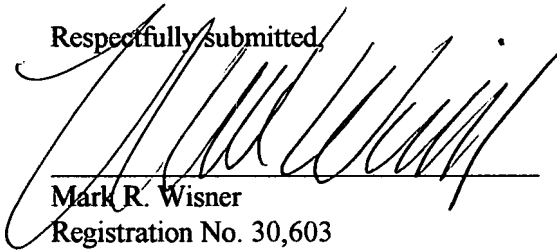
The §103 rejection of claims 19-21, 24, and 26 is also respectfully traversed. Contrary to the assertion (about one third of the way down page 5 of the Action) that the Ralph patents meet the claim language, there is no teaching or suggestion in the Ralph patents of biasing an insert that is mounted to an implant away from the implant after that device is introduced into the intervertebral space as recited in claim 19. To establish a proper *prima facie* showing of the obviousness of a claim requires, *inter alia*, that all the elements of the claim be disclosed in the prior art; in the absence of this claimed element, the §103 rejection of claim 19 is improper. Reconsideration and withdrawal of the §103 rejection of claim 19 over the Ralph patents is therefore respectfully requested.

The §103 rejection of the claims dependent upon claim 19 is also respectfully traversed. With respect to claims 20-21, reciting the filling of any space remaining after insertion of the claimed implant, because the device disclosed in the Muhanna patent is intended to replace the intervertebral disk, it is not understood how or why any space would need to be filled with a semi-solid or solid substance (as disclosed at col. 7, lines 3-19 of Muhanna) as asserted near the bottom of page 5 of the Action (again, attention is directed to the difference between total disk replacement as contemplated by Muhanna and the minimally invasive removal of a portion of the intervertebral disk for introduction of a device that cooperates with a portion of the disk in the intervertebral space as described above in connection with the present invention). With respect to claims 24 and 26, those claims are also dependent upon allowable claims and are themselves therefore allowable.

Entry of the above amendments, consideration of the remarks set out herein, allowance of the claims, and passage of the application to issuance are all respectfully requested. In the

unforeseen event that there are questions and/or issues yet to be answered in this application, it is respectfully requested that Applicant's Attorney be contacted at the address and phone number set out below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark R. Wisner', is written over a horizontal line.

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